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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,711	01/24/2000	David S. Roberts	PC10299A	6167

23913 7590 08/24/2005

PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/489,711	ROBERTS ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,16,17,24-27 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13, 16, 17, 24-27 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 04/15/05 in response to the non-final Office Action mailed 10/13/04.

Status of Claims

2) Claims 34-39 have been canceled via the amendment filed 04/16/05.

Claims 13, 17, 24-27 and 30 have been amended via the amendment filed 04/16/05.

Claims 13, 16, 17, 24-27 and 30-33 are pending and are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

5) The rejection of claims 35 and 36 made in paragraph 8 of the Office Action mailed 04/16/05 under 35 U.S.C § 112, first paragraph, as containing new matter, is moot in light of Applicants' cancellation of the claims.

6) The rejection of claim 39 made in paragraph 10 of the Office Action mailed 04/16/05 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claim.

7) The rejection of claims 34-39 made in paragraph 11 of the Office Action mailed 04/16/05 under 35 U.S.C § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C § 103(a) as being unpatentable over Frantz *et al.* (US 5,695,769- already of record) as evidenced by Barenholz *et al.* (US 6,156,337 - already of record), is moot in light of Applicants' cancellation of the claims.

8) The rejection of claim 34 made in paragraph 12(a) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

9) The rejection of claims 37 and 38 made in paragraph 12(c) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

10) The rejection of claim 34 made in paragraph 12(d) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claim 35 made in paragraph 12(i) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

12) The rejection of claim 36 made in paragraph 12(j) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

13) The rejection of claims 35-39 made in paragraph 12(k) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

14) The rejection of claims 24-27 made in paragraph 8 of the Office Action mailed 04/16/05 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claims.

15) The rejection of claims 13, 16, 17, 24-27 and 30-33 made in paragraph 11 of the Office Action mailed 04/16/05 under 35 U.S.C § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C § 103(a) as being unpatentable over Frantz *et al.* (US 5,695,769- already of record) as evidenced by Barenholz *et al.* (US 6,156,337 - already of record), is withdrawn upon further consideration. A modified rejection is set forth below.

16) The rejection of claims 13, 17 and 30 made in paragraph 12(a) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

17) The rejection of claims 32 and 33 made in paragraph 12(b) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim(s).

18) The rejection of claim 17 made in paragraph 12(d) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claim 16 made in paragraph 12(e) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn.

20) The rejection of claim 24 made in paragraph 12(f) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

21) The rejection of claims 26 and 27 made in paragraph 12(h) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

22) The rejection of claims 16, 24-27 and 31-33 made in paragraph 12(k) of the Office Action mailed 04/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claims.

Rejection(s) Maintained

23) The rejection of claims 17, 30 and those dependent therefrom, made in paragraph 9 of the Office Action mailed 04/16/05 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is maintained for reasons set forth therein and herebelow.

Applicants point to page 3, line 32 to page 4, line 2 of the specification and contend that the specification describes a preferred adjuvant which contains 'about 8% surfactant (e.g., 5.6% v/v Tween 80 and about 2.4% v/v Span 80'. Applicants assert that it is understood by those skilled in the art that Tween 80 and Span 80 are both examples of an amphiphilic surfactant.

Applicants conclude that the instant claims are adequately described in the specification in compliance with the written description requirement.

Applicants' arguments have been carefully considered, but are not persuasive. Claims 17 and 30 include the limitation: 'about 8% v/v of an amphiphilic surfactant'. The descriptive support at lines 26 and 27 on page 7 of the specification is limited to: 'an amphiphilic surfactant at from about 1.5% to about 6% v/v'. The descriptive support at line 1 of page 4 is for the limitation: 'about 8% v/v surfactant (e.g., about 5.6% v/v Tween 80 and about 2.4% v/v Span 80)'. This does not provide descriptive support for the limitation in the claims: about 8% v/v of an 'amphiphilic' surfactant. Tween 80 and Span 80 are limitations of narrower scope which do not provide support for the broad limitation 'amphiphilic surfactant', because the latter includes within its scope amphiphilic surfactants other than Tween 80 and Span 80. The full scope of 'amphiphilic surfactant' at about 8% v/v is not supported in the instant specification. The rejection stands.

Response to Applicants' Arguments on 35 U.S.C § 103 Rejection(s)

24) Applicants contend that: (a) Frantz *et al.* do not teach or suggest inactivating an *Erysipelothrix rhusiopathiae* with BPL. (b) The passing mention of BPL as an inactivating agent at line 12 of column 6 of Frantz *et al.* is understood to be applicable to inactivation of *P. multocida* and *B. bronchiseptica*. Where inactivation of *Erysipelothrix rhusiopathiae* is involved at columns 16 and 17 of Frantz *et al.*, only formalin is disclosed as the inactivating agent. (c) Those of skill in the art would not have reasonably expected that a BPL-inactivated fluid fraction of *Erysipelothrix rhusiopathiae* would have a sufficient immunoprotective effect. (d) Frantz *et al.* do not teach an *Erysipelothrix rhusiopathiae* vaccine that confers protection against *Erysipelothrix rhusiopathiae* infection. (e) Frantz *et al.* disclose the preparation of a fluid fraction of an inactivated *Erysipelothrix rhusiopathiae* culture, in which aluminum hydroxide was added to a final concentration of 25%. This preparation however was never applied to any animals to test its efficacy of protection. (f) Frantz *et al.* included only 0.3 ml of this *Erysipelothrix rhusiopathiae* preparation in a *P. multocida* vaccine of a total of 2 ml dose. (g) The *Erysipelothrix rhusiopathiae*-containing vaccine which induced best immunity in swine as described in Example 11, is the combination vaccine that was administered to swine, and the alleged protection

observed was against *P. multocida*. (h) There is no showing in Frantz *et al*. that the vaccine has any efficacy in protecting immunized animals against *Erysipelothrix rhusiopathiae*. (i) Frantz *et al*. do not teach a vaccine composition containing an inactivated *Erysipelothrix rhusiopathiae* fluid fraction with the specific adjuvant as presently claimed, i.e., an adjuvant with the specific amounts of specified ingredients as recited. Such a vaccine is stable and confers effective protection for an extended period of time. (j) The long -term protection conferred by such a vaccine is unexpected.

Applicants' arguments with regard to the disclosure of Frantz *et al*. have been carefully considered, but are not persuasive. The product claimed in claims 17, 24-27 and 30-33 is not produced by using BPL as the inactivating agent, and therefore Frantz *et al*. do not have to teach BPL to be the inactivating agent. The modified rejection made below addresses Applicants' arguments on the allegedly passing mention of BPL as an inactivating agent by Frantz *et al*. Applicants acknowledge in the instant specification the following to be known in the art: the use of inactivating agents 'known in the art', for example, formalin (formaldehyde), beta propriolactone, or other chemical agents having properties similar to these agents. See lines 17-19 on page 4 of the instant specification. Thus, not only Frantz *et al*. expressly suggested the use of beta-propiolactone as an alternative inactivating agent to inactivate the bacterial culture, but Applicants' admitted state of the prior art also acknowledges BPL to be an art-known inactivating agent alternative to formalin (formaldehyde). Given that the use of BPL as a bacterial inactivating agent is not critical for the instant invention as is evident from the description at lines 17-19 on page 4 of Applicants' specification, substitution of one inactivating agent with another, admittedly art-known, alternative inactivating agent was well within the realm of routine experimentation, would have been obvious to one of ordinary skill in the art, and would have brought about similar results or effects. The BPL-inactivated culture did not show any unexpectedly more effective protection in pigs compared to the formalin-inactivated cultures. See sentence bridging pages 11 and 12 of the instant specification. See the art rejection(s) made below.

With regard to Applicants' argument that Frantz's preparation was never applied to any animals to test its protective efficacy, the state of the art at the time of the invention should be

looked into. At the time of the instant invention, it was well known that protective antigens of *Erysipelothrix rhusiopathiae* are abundantly present in the culture filtrate, or rich in culture supernatant. See page 89, right column; and page 90, right column of Zarkasie *et al.* Therefore, the ability to protect an animal against *Erysipelothrix rhusiopathiae* is viewed as an inherent property inseparable from the prior art vaccine composition in light of what was well known in the art as taught by Zarkasie *et al.* See the art rejection(s) made below.

With regard to Applicants' arguments on the volume of the vaccine composition used, whether or not the volume of the vaccine administered in Frantz's method is 0.3 ml or 2 ml is not relevant since the volume of the vaccine composition is not a claim limitation. Even if one viewed Frantz's vaccine as a combination vaccine, such a vaccine is not excluded from the scope of the instant invention because of the open claim language used in the base claims: 'the antigen composition comprises'.

In sum, Frantz's disclosure meets the structural requirements of the claims drawn to a vaccine composition. Given the art-known stabilizing function of the aluminum hydroxide gel and given Zarkasie's disclosure of the abundant or rich presence of the protective antigens of *Erysipelothrix rhusiopathiae* in the culture filtrate or in the culture supernatant, the recited stability and the protective function are viewed as inherent properties inseparable from Frantz's vaccine composition. Although Frantz *et al.* are silent about the stability of the composition at 2°C to 8°C for at least one year and about the induction of immunity to weaned pigs for six months, these properties, not expressly recited by the prior art reference, are viewed as uncharacterized functions inherent to and inseparable from the prior art composition. Because Frantz's vaccine composition meets the structural limitations of the instant claims, it is expected to have the same functional properties with regard to the duration for which it remains stable and the immunity or protection conferred.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

25) Claims 17, 30 and those dependent therefrom are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

There appears to be no descriptive support within the instant specification for the newly added recitations in claims 17 and 30: 'said vaccine composition protects an animal against *Erysipelothrix rhusiopathiae* infection'. The protection conferred by the vaccine composition that is described on page 21 of the specification is limited to pigs that are 9 weeks of age. The term 'pigs' does not provide support for the limitation of much broader scope, 'an animal'. Therefore, the above-identified limitations in claims 24-27, 35 and 36 are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the above-identified limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C § 112, Second Paragraph

26) Claims 25, 27 and 30-33 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 31 is vague and confusing in the limitation 'provides immunity to weaned pigs'. Claim 31 depends from claim 30, which as amended, includes the limitation: 'protects an animal against *E. rhusiopathiae* infection'. It is unclear how the broader term 'immunity' in claim 31 further limits the limitation 'protection' from claim 30.

(b) Claim 25 is confusing and/or has improper antecedence in the limitation: 'the concentrated composition'. Claim 25, as amended, depends from claim 24, which does not recite any 'concentrated' composition.

(c) Analogous criticism applies to claim 27.

(d) Claim 30 has improper antecedence in the limitation: 'the culture fluid fraction', because there is no earlier recitation of 'a culture fluid fraction' in the claim.

(e) Claim 30 is incorrect in reciting a comma after the limitation 'and,' in line 8 of the claim. It is suggested that Applicants replace the limitation with --and--.

(f) Claims 31-33, which depend from claim 30, are also rejected as being indefinite

because of the indefiniteness or vagueness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

27) Claims 17, 24-27 and 30-33 are rejected under 35 U.S.C § 102(b) as being anticipated by Frantz *et al.* (US 5,695,769- already of record) as evidenced by Barenholz *et al.* (US 6,156,337 - already of record) and Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-89, 1996, already of record).

The term 'about' with regard to the percent v/v of the stabilizing agent, or the adjuvant ingredients recited in the instant claims, is interpreted in this rejection as encompassing $\pm$ 10.

Frantz *et al.* disclosed a vaccine composition comprising a culture fluid fraction obtained from a culture of *Erysipelothrix rhusiopathiae* inactivated by formalin. The fraction is clarified by centrifugation and therefore is substantially free of cells of *Erysipelothrix rhusiopathiae*. The fluid antigen fraction is then concentrated by ultrafiltration to a calculated OD of 16.67. See sections 'B. Inactivation of Bacteria' and 'C. Vaccine Fluid Preparation' at the upper half of column 17. The antigen composition further comprises an aluminum hydroxide gel carrier, i.e., REHYDRAGEL or REHYDRAGEL HPA, or calcium phosphate, or alum at a concentration of between 15 and 60% (see lines 55-65 in column 6; paragraph bridging columns 6 and 7; and the first full paragraph in column 7) and a saponin adjuvant (see claim 7; and lines 41-43 in column 5). The antigen composition comprises saline, Drakeol, i.e., lecithin and mineral oil emulsion at various concentrations, and between 0.7% to 3.2% Tween 80 and 0.3% to 1.8% Span. The lecithin and mineral oil emulsion is present at a concentration of 5 to 40%, or 10% (see claims and second full paragraph in column 21), or 8% v/v of amphiphilic surfactant (see the Table in column 19). The *Erysipelothrix rhusiopathiae* antigen-containing vaccine induced best immunity in swine (see Example 11). Frantz *et al.* expressly taught that other inactivating agents, such as, betapropiolactone may be used as an alternative inactivating agent to formalin or formaldehyde solution (see the first full paragraph in column 6). That aluminum hydroxide in Frantz's composition intrinsically served as a stabilizing agent is inherent from the teachings of Frantz *et al.* in light of what was known in the art. For instance, Barenholz *et al.* taught the dual role of aluminum hydroxide both as an adjuvant and as a stabilizer in microbial vaccines (see column 13, last two lines). The ability to protect an animal against *Erysipelothrix rhusiopathiae* is viewed as an inherent property inseparable from the prior art vaccine composition in light of what was well

known in the art. For instance, Zarkasie *et al.* expressly taught that protective antigens of *Erysipelothrix rhusiopathiae* are abundant in the culture filtrate (see page 89, right column), or rich in culture supernatant (see page 90, left column). Therefore, Frantz's disclosure meets the structural requirements of the claims. Given the stabilizing function of the aluminum hydroxide gel and given Zarkasie's disclosure of the abundant or rich presence of the protective antigens of *Erysipelothrix rhusiopathiae* in the culture filtrate or in the culture supernatant, the recited stability and the protective function are viewed as inherent properties inseparable from Frantz's vaccine composition. Although Frantz *et al.* are silent about the stability of the composition at 2°C to 8°C for at least one year and about the induction of immunity to weaned pigs for six months, these properties not expressly recited by the prior art reference, are viewed as uncharacterized functions inherent to and inseparable from the prior art composition. Because Frantz's vaccine composition meets the structural limitations of the instant claims, it is expected to have the same functional properties with regard to the duration during which it remains stable and the immunity or protection conferred.

Claims 17, 24-27 and 30-33 are anticipated by Frantz *et al.*

Rejection(s) under 35 U.S.C § 103

28) Claims 13 and 16 are rejected under 35 U.S.C § 103(a) as being unpatentable over Frantz *et al.* (US 5,695,769- already of record) in view of Applicants' admitted state of the prior art, and Barenholz *et al.* (US 6,156,337 - already of record).

Frantz *et al.* disclosed a vaccine composition comprising a fluid fraction obtained from a fluid fraction of a culture of *Erysipelothrix rhusiopathiae* inactivated by formalin. The fraction is clarified by centrifugation and therefore is substantially free of cells of *Erysipelothrix rhusiopathiae*. The fluid antigen fraction is then concentrated by ultrafiltration to a calculated OD of 16.67. See sections 'B. Inactivation of Bacteria' and 'C. Vaccine Fluid Preparation' at the upper half of column 17. The antigen composition further comprises an aluminum hydroxide gel carrier, i.e., REHYDRAGEL or REHYDRAGEL HPA, or calcium phosphate, or alum (see lines 55-65 in column 6; paragraph bridging columns 6 and 7; and the first full paragraph in column 7). Frantz *et al.* expressly taught that other inactivating agents, such as, betapropiolactone, may be used as an alternative inactivating agent to formalin or formaldehyde solution (see the first full

paragraph in column 6). That aluminum hydroxide in Frantz's composition intrinsically served as a stabilizing agent is implicit from the teachings of Frantz *et al.* in light of what was known in the art. For instance, Barenholz *et al.* taught the dual role of aluminum hydroxide both as an adjuvant and as a stabilizer in microbial vaccines (see column 13, last two lines).

The teachings of Frantz *et al.* are explained above which do not expressly disclose BPL as the inactivating agent used to inactivate the *Erysipelothrix rhusiopathiae* culture.

However, inactivation of bacteria with an inactivating agent alternative to formalin or formaldehyde solution, such as, betapropiolactone, was routine and conventional in the art at the time of the invention. For instance, Applicants acknowledge in the instant specification the following to be known in the art: the use of inactivating agents 'known in the art', for example, formalin (formaldehyde), beta propriolactone, or other chemical agents having properties similar to these agents. See lines 17-19 on page 4 of the instant specification.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the admittedly art-known BPL inactivating agent or Frantz's BPL inactivating agent to inactivate Frantz's *Erysipelothrix rhusiopathiae* culture to produce the antigen composition and the vaccine of the instant invention, with a reasonable expectation of success, because not only Frantz *et al.* expressly suggested the use of beta-propiolactone as an alternative inactivating agent to inactivate the bacterial culture, but Applicants' admitted state of the prior art also acknowledges BPL to be an art-known inactivating agent alternative to formalin (formaldehyde). Given that the use of BPL as a bacterial inactivating agent is not critical for the instant invention as is evident from the description at lines 17-19 on page 4 of Applicants' specification, substitution of one inactivating agent with another, admittedly art-known, alternative inactivating agent was well within the realm of routine experimentation, would have been obvious to one of ordinary skill in the art, and would have brought about similar results or effects.

Claims 13 and 16 are *prima facie* obvious over the prior art of record.

Remarks

29) Claims 13, 16, 17, 24-27 and 30-33 stand rejected.

30) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300.

31) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

32) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

August, 2005

S. DEVI, PH.D.
PRIMARY EXAMINER